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Message:

Re: U.S. Serial No. 09/745,017
Our Reference: 37974-0167

Dear Examiner Whisenant:

Pursuant to your request, attached is a list of claims that we believe are allowed in the captioned application. Please note that there is no claim 38. We also believe that claims 41-43 are allowed, however, they were not listed on the Notice of Allowability dated June 27, 2003. We are missing page 2 of the Notice of Allowability and would appreciate it if you would fax it to us as soon as possible. Please contact John Isacson at (202-912-2777) to discuss this matter further.

Regards,
Denise Mayhew
Patent Assistant to John Isacson

U.S. Serial No. 09/745,017
Allowed Claims

1. A method for determining the type of target nucleic acids in a sample, wherein the method is capable of differentiating free and encapsulated target nucleic acids in the sample, wherein the method comprises

(a) determining a total target nucleic acid content in the sample;

(b) adding a nuclease to the sample to digest free target nucleic acids in the sample to form a nuclease-treated sample;

(c) determining a total target nucleic acid content remaining in the nuclease-treated sample, thereby quantifying the amount of encapsulated target nucleic acids in the sample; and

(d) quantifying the total amount of free target nucleic acid in the sample by subtracting the determined amount of target nucleic acid content in the nuclease-treated sample from the determined amount of total target nucleic acid content in the sample, wherein steps (c) and (d) determine the types of target nucleic acids in the sample.

3. The method of claim 1, wherein all determining of the target nucleic acids is performed using a nucleic acid amplification assay selected from the group consisting of a polymerase chain reaction (PCR) assay and a reverse transcriptase (RT) PCR assay.

4. The method of claim 1, further comprising adding a nucleic acid standard to the sample before the total target nucleic acid content of (a) is determined.

5. The method of claim 1, further comprising adding a nucleic acid standard to the sample after the free target nucleic acids in the sample are digested with the nuclease.

6. The method of claim 1, wherein the nuclease is inactivated after the free nucleic acids in the sample are digested.

7. The method of claim 1, wherein the nuclease is a DNase or an RNase.

8. The method of claim 1, wherein the sample is selected from the group consisting of blood, plasma, serum, cell culture fluids, cells and a pharmaceutical preparation.

21. A method for determining the proportion of infectious pathogens and inactivated pathogens in a sample, wherein the method is capable of differentiating free and encapsulated target nucleic acids in the sample, wherein the method comprises

(a) determining a total target nucleic acid content in the sample;

(b) adding a nuclease to the sample to digest free target nucleic acids in the sample to form a nuclease-treated, wherein the nuclease will not digest the encapsulated target nucleic acids;

(c) determining a total target nucleic acid content remaining undigested in the nuclease-treated sample, which represents the amount of infectious pathogens in the sample;

(d) quantifying the total amount of free target nucleic acid in the sample by subtracting the determined amount of undigested target nucleic acid content in the nuclease-treated sample from the determined amount of total target nucleic acid content in the sample, wherein the quantifying indicates the amount of inactivated pathogens in the sample; and

(e) comparing the amounts from steps (c) and (d) to determine the proportion of infectious pathogens and inactivated pathogens in the sample.

23. The method of claim 21, wherein all determining of the target nucleic acids is performed using a nucleic acid amplification assay selected from the group consisting of a polymerase chain reaction (PCR) assay and a reverse transcriptase (RT) PCR assay.

24. The method of claim 21, further comprising adding a nucleic acid standard to the sample before the total target nucleic acid content of (a) is determined.

25. The method of claim 21, further comprising adding a nucleic acid standard to the sample after the free target nucleic acids in the sample are digested with the nuclease.

26. The method of claim 21, wherein the nuclease is inactivated after the free nucleic acids in the sample are digested.

27. The method of claim 21, wherein the nuclease is a DNase or an RNase.

28. The method of claim 21, wherein the sample is selected from the group consisting of blood, plasma, serum, cell culture fluids, cells and a pharmaceutical preparation.

29. The method according to claim 21, wherein the pathogen is a virus.

30. The method according to claim 29, wherein the virus is selected from the group consisting of parvovirus, hepatitis virus and human immunodeficiency virus.

31. A method for detecting infectious pathogens in a sample, wherein the method comprises

(a) determining a total target nucleic acid content in the sample;

(b) adding a nuclease to the sample to digest any free target nucleic acids in the sample to form a nuclease-treated sample, wherein the nuclease will not digest the encapsulated target nucleic acids; and

(c) detecting infectious pathogens that may be present in the sample by determining a total target nucleic acid content remaining in the nuclease-treated sample, which represents the amount of infectious pathogens in the sample.

33. The method of claim 31, wherein all determining of the target nucleic acids is performed using a nucleic acid amplification assay selected from the group consisting of a polymerase chain reaction (PCR) assay and a reverse transcriptase (RT) PCR assay.

34. The method of claim 31, further comprising adding a nucleic acid standard to the sample before the total target nucleic acid content of (a) is determined.

35. The method of claim 31, further comprising adding a nucleic acid standard to the sample after the free target nucleic acids in the sample are digested with the nuclease.

36. The method of claim 31, wherein the nuclease is inactivated after the free nucleic acids in the sample are digested.

37. The method of claim 31, wherein the nuclease is a DNase or an RNase.

[THERE IS NO CLAIM 38.]

39. The method of claim 31, wherein the sample is selected from the group consisting of blood, plasma, serum, cell culture fluids, cells and a pharmaceutical preparation.

40. The method according to claim 31, wherein the pathogen is a virus.

[Claim 41 was added in the Amendment filed on November 18, 2002, however, it is not listed on the Notice of Allowability dated June 27, 2003.]

41. The method according to claim 40, wherein the virus is selected from the group consisting of parvovirus, hepatitis virus and human immunodeficiency virus.

[Claims 42 and 43 were added in the Amendment filed on June 3, 2003, however, they are not listed on the Notice of Allowability dated June 27, 2003.]

42. The method of claim 31, wherein samples that have acceptable levels of infectious pathogens are used for the preparation of biological products.

43. The method of claim 31, wherein samples that have unacceptable levels of infectious pathogens are discarded or subjected to at least one of a pathogen inactivation treatment or a pathogen removal treatment.